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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,609	06/12/2001	Shuyuan Zhang	INRP:081USD1	7626

7590 02/07/2005

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EXAMINER
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MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/880,609	Applicant(s) ZHANG ET AL.	
	Examiner Mary E. Mosher, Ph.D.	Art Unit 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 26 November 2004.

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 30-49 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☒ Claim(s) 30 is/are allowed.

6) ☒ Claim(s) 31-49 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All    b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/26/04 (2).

4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/2004 has been entered.

### ***Priority***

Applicant has restored the priority claim to 09/203,078 filed December 1, 1998, and disclaimed priority to earlier applications. Therefore the effective date is December 1, 1998.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 11/26/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,726,907 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Rejections - 35 USC § 112***

Claims 31-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions with 0.4-10 ng of contaminating human DNA per  $10^{12}$  virus particles, does not reasonably provide enablement for the lower range of 50 pg. The specification does not enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification and original claims express a desire for a product with only 50 pg of contaminating human DNA. However, in the working examples, the lowest amount obtained is 4 ng (400 pg) on page 169. The specification states on page 100 that a "developmental batch" has 80 pg/mL, but does not relate that to virus particles/mL or indicate which of the "purification techniques in accordance with the present disclosure" were used to obtain this product. Since the methods taught in the specification did not actually achieve the purity level recited in the claim, it is concluded that undue experimentation would be required to exceed the purity shown in the working examples.

#### ***Allowable Subject Matter***

Claim 30 is allowed. Carrion et al US 6383795 is cited as the closest prior art, in teaching a large-scale purification method for adenovirus. The patent includes an example where cells are grown in serum-free medium, which would result in a BSA-free product; however, this embodiment is not taught in the provisional priority document, therefore the specific teachings needed to render the invention obvious are not prior to applicant's effective date.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2/2/05



MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800-1600